

## **REMARKS**

As an initial matter, Applicant appreciates the thorough examination by the Examiner.

### **The Examiner's Objections**

The Examiner objects to the drawings and particularly with respect to Figure 1. The Examiner states that the drawings must show every feature of the invention as specified in the claims under 37 CFR 1.83(a). Specifically, the Examiner argues that the pressure adjusters 13 and speed adjusters 14 are not depicted in Figure 1. Further, the Examiner argues that Figure 1 fails to show the numbering of the valves 12 as described in the specification.

In response to the Examiner's objections, Applicant submits a Replacement Sheet depicting the pressure adjusters 13 and speed adjusters 14 as set forth in the claims, and the valves 12 as set forth in the specification.

### **The Examiner's Rejections**

The Examiner rejects claims 1-3 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,431,620 to Schenck in view of U.S. Patent No. 5,478,479 to Herrig.

The Examiner also rejects claims 4-7 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,035,708 to Alchas in view of Schenck and further in view of Herrig.

In response to the Examiner's rejections, Applicant submits amended claims and addresses the Examiner's concerns herein below.

### **Replacement Sheet Depicts Appropriate Figure 1**

As noted above, Examiner argues that the pressure adjusters 13 and speed adjusters 14 set forth in the claims are not depicted in Figure 1. Further, the Examiner argues that Figure 1 fails to show the numbering of the valves 12 as described in the specification.

Applicant submits that the attached Replacement Sheet illustrating Figure 1 properly illustrates the pressure adjusters 13 and speed adjusters 14 as set forth in the claims, and the valves 12 as set forth in the specification

### **Amended Independent Claim 1 is Not Obvious**

The Examiner rejects, among others, independent claim 1 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,431,620 to Schenck in view of U.S. Patent No. 5,478,479 to Herrig. Applicant disagrees with the Examiner's assessment of the structure and function of Schenck and Herrig for the reasons set forth below.

#### ***Schenck***

U.S. Patent No. 5,431,620 to Schenck discloses a centrifuge system and method for measuring and then adjusting various process parameters of a centrifugal operation (i.e., windage, temperature, and moment of inertia). Referring to Figure 1, the system includes a centrifuge 10 having a housing 32 mounted to a sleeve 44, a hub 26 connecting a rotor 16 to a drive shaft 14 and motor 12, and a vacuum pump 36 in communication with the interior atmosphere of the housing (i.e., centrifuge chamber). The vacuum pump communicates with the interior of the housing via a first annular gap 54, a second annular gap 56, and a conduit 38 to thereby create a vacuum (or near vacuum) in the centrifuge

chamber. The rotor includes containers 18 and 20 for receiving samples. Refrigeration coils 33 provide temperature adjustment within the centrifuge chamber.

In operation, the vacuum pump evacuates air from the centrifuge chamber upwardly into the second annular gap 56 and then downwardly into the first annular gap 54, whereafter evacuated air is channeled to the vacuum pump 36.

In particular, the system and method measures one or more physical characteristics of a rotor to accomplish the following:

(1) determine windage (i.e., power consumed in pumping the gaseous atmosphere surrounding the rotor) and thereafter adjust a vacuum system based upon changes in the rotational speed of the rotor;

(2) determine windage and thereafter adjust temperature within the compartment by way of a refrigeration circuit and coils; and

(3) determine windage and thereafter adjust adaptive circuitry of the centrifuge drive system.

*See Abstract; Col. 4, lines 32-38; Col. 4, line 67 to Col. 5, lines 1-2; and Col. 5, lines 61-62.*

Accordingly, Schenck discloses a centrifuge for optimizing centrifugal operations by measuring windage and then adjusting air pressure and temperature within the chamber as well as adjusting circuitry operating the centrifuge drive system. Schenck fails to disclose a centrifuge having an external unit for performing liposuction and lipoinjection, wherein the external unit is a fat injection vessel. As configured, the sole function of Schenck is centrifugation and the optimization of that operation.

***Herrig***

U.S. Patent No. 5,478,479 to Herrig discloses a system and method of washing salvaged blood that incorporates a variety of lines 26, 21, 30, 32 in communication with a patient's wound 12a, a vacuum 19, a salvaged blood reservoir 16, an anticoagulant bag 14, a wash solution bag 18, a pump P, and a centrifuge bowl 20 operated by a motor 23. Herring further provides an optical line sensor 7 connected to the salvaged blood reservoir and controlling the speed of the pump, the number of wash stages, and the volume of wash solution employed for washing blood components.

Contrary to the Examiner's interpretation, Herrig fails to disclose—much less suggest—“a tissue suction and injection system.” Office Action, page 5. In fact, Herrig discloses a system for washing and separating blood salvaged from an injured person.

In stark contrast, the present invention incorporates a fat injection vessel for performing liposuction and lipoinjection in communication with a centrifuge for filtering fat from collected tissue. Herrig neither discloses nor teaches a system for performing liposuction or lipoinjection, wherein a pump and valves communicate with an external unit that suctions fat, centrifuges collected tissue, and thereafter injects filtered fat into a patient.

***Schenk and Herrig Fail to Disclose an Integrated Controlled System and Method for Sequentially Performing Liposuction, Centrifugation, and Lipoinjection***

In contrast to Schenk, the present invention provides a system and method for sequentially performing liposuction, centrifugation, and lipoinjection wherein the system is integrated into a single unit and includes a controller for controlling a pump and centrifuge. Stated differently, the present invention relies upon a single controller to vary suction and compression as well as centrifugation. As configured, the invention incorporates a fat injection vessel having a syringe and cannula such that a user can

perform liposuction, obtain filtered fat by centrifugation, and thereafter perform lipoinjection during one operation and relying upon a single instrument.

In contrast to the Examiner's assertion, Schenk fails to disclose a fat injection vessel. In fact, the Examiner has mislabeled Applicant's "external unit" as a drive motor. Office Action, page 4, paragraph 6. In fact, Applicant's drive motor is drive unit 4 as illustrated in Figure 1.

Furthermore, Schenk fails to disclose a fat injection vessel (i.e., external unit) in communication with a centrifuge housing, wherein the system sequentially performs liposuction, centrifugation, and lipoinjection as set forth in amended claim 1.

Schenk further fails to disclose a controller for selectively operating a drive unit of the centrifuge and a pump device.

Schenk also fails to disclose a pump that provides suction and compression to a fat injection vessel (i.e., external unit) as set forth in amended claim 1. Rather, Schenk discloses a pump for creating a vacuum (or near vacuum) within the centrifuge chamber. Thus Schenk teaches a pump for affecting the centrifuge chamber and not a fat injection vessel.

Moreover, Schenk fails to disclose a centrifuge wherein a single controller controls the drive unit and pump—i.e., the suction, centrifugation, and compression operations as set forth in amended claim 1.

Still further Schenk fails to suggest an integral system for performing vacuum, centrifugation, and compression as set forth in amended claim 1. Schenk merely discloses a centrifuge having sensors for measuring and thereafter adjusting pressure and temperature to achieve optimal centrifugation.

Finally, Herring fails to disclose a system for tissue suction and injection system incorporating valves and an air pump. Rather, Herring merely discloses a system for

washing salvaged blood collected from a wound by separating blood components in a centrifuge.

The combination fails to disclose Applicant's centrifuge that performs liposuction, centrifugation, and lipoinjection by providing an integrated external unit in the form of a fat injection vessel, wherein a single controller (1) selectively varies operation of the centrifugal device and (2) selectively varies the amount of vacuum and compression provided to the external unit.

Accordingly, Applicant submits that amended claim 1, and claims 2-3 depending therefrom, are not obvious.

#### **Amended Independent Claim 4 is Not Obvious**

The Examiner also rejects claims 4-7 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,035,708 to Alchas in view of Schenck and further in view of Herrig.

#### ***Alchas***

Alchas discloses an endothelial cell procurement deposition kit for collecting fat, processing the fat to produce an endothelial cell deposition product, and depositing the product on the surface of a graft. Alchas fails to teach lipoinjection by means of an external unit having a syringe and cannula. In fact, Alchas makes no reference to the step of performing lipoinjection. More accurately, Alchas teaches the step of transplanting endothelial cell lining onto the surface of a vascular graft during surgery.

#### ***Schenck and Herring are Improper References and Cannot Be Combined with Alchas***

The Examiner alleges that it would have been obvious to modify or combine Alchas in combination with Schenck and Herrig for the purpose of streamlining the

procedure of liposuction and lipoinjection. Having set forth the structural and functional differences between Schenck and Herring, and the subject invention, Applicant submits that both cited patents are improper references under §103(a). Accordingly the Examiner's rejection of claims 4-7 under §103(b) in reliance upon Alchas, Schenck, and Herring is now improper.

That said, even assuming Schenck and Herring were proper and combined with Alchas, the combination fails to disclose a method for sequentially performing liposuction, centrifugation, and lipoinjection wherein the method incorporates an integrated apparatus as set forth in amended claim 1. Because the system is a single integral unit, the sequential method of the present invention permits the operator to create low compression when injecting fat into subcutaneous fat layers, and high compression when injecting fat into muscularis.

The combination of the cited references also fails to disclose a method wherein a single controller communicates with a pump and a centrifuge to vary suction and compression—as well as centrifugation—in response to an operator's input. Moreover, nothing in the cited art discloses a controller for automatically varying pressure to a fat injection vessel in response to an operator's input by means of a series of valves.

The combination of the cited art would provide a non-integral system and method including a centrifuge, a pump for creating a vacuum or near vacuum in the centrifuge chamber, a series of lines and valves for directing blood to and from the centrifuge, a fat collection unit lacking input from a controller capable of varying selectable pressure, wherein the method includes the steps of collecting blood and/or fat, and then depositing the treated blood and/or fat in the lumen (i.e., space inside a blood vessel) of a graft (i.e., a piece of living tissue). Applicant claims no such device or method.

Thus, Applicant submits that amended claim 4, and claims 5-7 depending therefrom, are not obvious.

**Amended Independent Claim 1 is Patentable**

Amended independent claim 1 now recites a centrifuge having a centrifugal device integrated with an external unit (i.e., hand-held fat injection vessel) and a pump, wherein a single controller selectively operates a drive unit of the centrifuge and the pump to perform vacuum, centrifugation, and compression operations, and wherein the centrifuge performs these operations in a sequential fashion.

Schenk in combination with Herrig fails to disclose the system described in amended independent claim 1—and in particular fails to disclose an external unit of the type claimed herein—and therefore must be removed as proper §103(a) references. Accordingly, Applicant submits that amended claim 1 is not obvious and is now allowable.

**Amended Independent Claim 4 is Patentable**

Amended independent claim 4 now recites a method of performing liposuction, centrifugation, and lipoinjection using a centrifugal device integrated with a fat injection vessel and a pump, wherein a single controller selectively operates a drive unit of the centrifuge and the pump to perform vacuum, centrifugation, and compression operations, and wherein the centrifuge performs these operations in a sequential fashion.

Alchas in combination with Schenk and Herrig fails to disclose the system described in amended independent claim 1 and therefore must be removed as proper §103(a) references. Accordingly, Applicant submits that amended claim 4 is not obvious and is now allowable.



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### **CONCLUSION**

Based on foregoing amendments and arguments, Applicant submits that pending claims 1-7 are now in immediate condition for allowance, and the same is respectfully requested.

Respectfully submitted,

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